

PUBLIC INFORMATION & COMMUNICATION SERVICES (PICS)
NIH - TASK ORDER

RFTOP#101

TITLE: Developing a Comprehensive Evaluation of the NIH Responsible Conduct of Research (RCR) Requirement under National Research Service Award Institutional Research Training Grants

PART I – REQUEST FOR TASK ORDER (TO) PROPOSALS

A. Point of Contact:

Ms. Valerie Pickett

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Proposal Address:

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Bethesda, MD 20892-7540
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Billing Address:

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B. PROPOSED PERIOD OF PERFORMANCE:

One year from the date of the award.

C. PRICING METHOD:

Time and Materials. Available funding is limited to \$250,000. A firm that is able to meet all the objectives and complete all the tasks for less than that amount is invited to propose a lower price for the successful execution of this task. Price will be a consideration in the determination of the firm that is selected for award. NIH is of the opinion that this funding is adequate, but if in the opinion of your firm this is not a sufficient amount to successfully achieve the stated objectives, please specify which objectives can be completed, which tasks will remain undone, and the additional amounts necessary to complete the requirement. Firms should specify the approach(s) that they would employ and address the benefits and drawbacks of alternate approaches.

D. PROPOSAL INSTRUCTIONS:

Proposals should be submitted to the Point-of-Contact shown above by e-mail. Please enter in the subject line the following text, "RFTOP# 101- Proposal from {insert your firm's name}." A signed task order form may be scanned and submitted or will later be requested from the selected firm.

E. RESPONSE DUE DATE:

September 23, 2002 at 9:00 AM, NIH local time.

F. TASK DESCRIPTION:

Background: Since July 1990, the NIH has required all graduate students and postdoctorates supported by NRSA institutional research training grants to receive education in the Responsible Conduct of Research (RCR). In 1992, (see <http://grants1.nih.gov/grants/guide/notice-files/not92-236.html>) the requirement was updated to specify that applications for training grant support that did not include plans for RCR instructions would be considered incomplete and would be returned to the applicant institution without review. The NIH did not specify the content or the format of the required training and allowed the institution to tailor RCR instruction to ensure consistency with the nature of the overall research training program. For example, if the research training involved human subjects, one might expect a greater depth of the instruction focused on issues associated with protection of human subjects than if the research training focused on the determination of protein structure. The NIH policy did, however, suggest inclusion of the following topics: conflict of interest, responsible authorship, policies for handling research misconduct, policies and requirements associated with research involving human and animal subjects, and data management. The NIH policy announcement also gave applicants a great deal of latitude in terms of the format and frequency of the instruction. This flexibility stimulated the development of a number of different approaches and prompted several studies about the nature of RCR training (see sample references shown below).

Review of RCR Plans: The RCR training plan in training grant applications is judged on the content, frequency and quality of the proposed approach. The RCR segments of the application are reviewed after the overall technical and educational merit of the application has been assessed and a priority score has been determined. This approach, allows reviewers to provide a very clear indication of the quality of description of the training plan provided in the application. It also permits the NIH to exert a greater level of oversight over the type of RCR instruction provided. In some cases, even the most technically meritorious training grant applications have remained while the applicant develops a better plan for instruction in RCR.

The purpose of this request for task order proposals is to begin a systematic examination and evaluation of RCR training methods. The goal is to develop a sense of how RCR training is being delivered and how much research has already been conducted. The task order contractor will conduct an exhaustive search of the literature in order to prepare a bibliography and a brief summary of existing material related to the nature of or evaluations of existing RCR training programs (see sample reference list below). Material of interest will include any assessments or descriptions of content, objectives, the skills of the instructors, the frequency and format of delivery, and other important factors associated with RCR instruction. The assembly and collation of existing information will help identify common goals and document the accomplishments of existing programs. It will also provide information related to the evaluation of existing programs.

These data will be organized into a coherent, logical format to be shared with experts in the area of RCR training and program evaluation to develop identify common goals for the NRSA instructional requirement and develop a set of variables and outcome indicators associated with the attainment of the identified goals. Based on the advice of the experts, the contractor will design and prepare a plan for a comprehensive evaluation of the overall RCR requirement. Ultimately, the evaluation plan will be used to collect information from existing NRSA training programs in order to broadly assess the effectiveness of RCR instruction. This comprehensive evaluation will permit an identification of instructional approaches that are most efficient and may lead to the modification of policies and requirements to successfully attain the identified goals.

Sample References: A number of studies (including those listed below) have partially identified educational approaches and tested the effects of RCR training on perceptions, practices, and attitudes regarding ethical issues:

- Bebeau MJ with Pimple KD, Muskavitch KMT, Borden SL, Smith DH (1995): Moral Reasoning in Scientific Research: Cases for Teaching and Assessment; Indiana University (<http://www.indiana.edu/~poynter/mr-main.html>).
- Brown S, Kalichman MW (1998): Effects of training in the responsible conduct of research: A survey of graduate students in experimental sciences. *Science and Engineering Ethics* 4: 487-498
- Eastwood S, Derish P, Leash E, Ordway S (1996): Ethical issues in biomedical research: perceptions and practices of postdoctoral research fellows responding to a survey. *Science and Engineering Ethics* 2: 89-114.
- Kalichman MW, Friedman PJ (1992): A pilot study of biomedical trainees' perceptions concerning research ethics. *Academic Medicine* 67: 769-775.
- Mastroianni AC, Kahn JP (1998): The Importance of Expanding Current Training in the Responsible Conduct of Research. *Academic Medicine* 73: 1249-1254

Approach: The Task Order Contractor will carry out the following tasks:

1. Within 10 business days of the award of this contract the Task Order Contractor will meet with the project officers to initiate discussions about the RCR training requirement, the existing literature, plans for the workshop, and clarify requirements for the development of an evaluation plan. This meeting will also be used to review work schedules, personnel assignments, early project activities and project priorities.
2. Within 5 business days of the initial meeting deliver a timeline for the preparation of a comprehensive bibliography, development of a plan and draft agenda for the workshop, and a plan for the preparation of the final evaluation proposal. The timeline will also include additional details about work schedules and personnel assignments throughout the project period.
3. The contractor will, with approval from the project officers, select a site for a two day workshop involving 25 to 30 participants and speakers including 10 to 12 federal employees. This site must be close to an airport or metro station in the Washington, DC area. Meeting space rental will use funds allocated under this contract. The contractor will negotiate and implement a contract to obtain high quality meeting space. All lodging and per diem shall be contracted at rates in accordance with Federal Travel Regulations. Required services may include any necessary audio-visual, telecommunications, computer and recording equipment, along with any requested supplies such as easels, pointers, note pads, reference documents, etc. for the workshop speakers and participants. Coordination of food and beverage services may be required as part of the workshop agenda, but the NIH will not provide any direct contract funds for food and beverages. The contractor will maintain contact with the project officers at the workshop to ensure smooth operations.
4. The contractor, working with the project officers, will develop a participant and speaker list for the workshop. Participants and speakers will include experts in the field of program evaluation as well as experts in the fields of bioethics, RCR training, and adult education. Participants and speakers will be selected to represent a wide range of theoretical perspectives.
5. The contractor will prepare and distribute pre-registration materials to participants and shall prepare a detailed agenda as well as a list of all speakers and participants including appropriate contact information. The contractor will produce and distribute all necessary workshop announcements and materials. The information will include instructions

for participants on reserving rooms, directions to the hotel from local airports, and a list of restaurants near the hotel. The contractor will handle registration at the workshop site. The contractor will provide all workshop materials including but not limited to announcements agenda, participant information packets, table name signs, name badges, etc. Expenses associated with travel, lodging, and a \$200/day honorarium for external participants and speakers will be the responsibility of the contractor.

6. With the approval of the project officers, the contractor will invite and confirm workshop participants and speakers (25 to 30 including 10 to 12 federal employees). The contractor will make travel and lodging arrangements for the external participants and speakers.
7. The contractor shall provide post-workshop services including fiscal management, public relations, and mailing thank-you letters to the participants and speakers.
8. At least 60 days prior to the workshop, the contractor will deliver a draft of a comprehensive (and briefly annotated) bibliography of publications and resources associated with RCR instruction to the project officers. The document will include information pertaining to existing knowledge related to the RCR requirement in terms of content, format, frequency, duration, attendance requirements, goals, and assessments. It will help establish the range of practice and it will assist with the development of a list of variables for a more comprehensive evaluation. In addition, this document will serve as background information for a workshop designed to assist with the development of a plan to evaluate the NRSA RCR training requirement. The contractor will work with the project officers to finalize the bibliography for presentation to the workshop participants.
9. At least 30 days prior to the workshop, the contractor will mail the annotated bibliography along with other pre-registration materials to the workshop participants. The contractor will also provide copies of any existing descriptive analyses or evaluative studies (published or unpublished) of the RCR requirement to workshop participants at this time. In the case of unpublished studies, participants will be asked not to reveal the contents outside the workshop and where possible, the authors of such studies will be asked to present their findings at the workshop.
10. The contractor will provide an expert(s) in evaluation methodology who will participate in and moderate the workshop. The expert will serve as a moderator for the workshop and will attempt to elicit guidance from the workshop participants regarding the identification of RCR instructional

goals, relevant programmatic outcome variables and metrics related to the attainment of those goals, and an overall evaluation plan that includes data collection and analysis. The evaluation plan will help define research questions that will extend existing knowledge about the effectiveness of RCR instruction.

11. Finally, based on the recommendations of the workshop participants, the contractor will work with the Project Officers to develop a detailed evaluation plan to assess the training grant RCR education requirement. Using the goals and objectives defined in the workshop, the contractor will develop a written evaluation plan that will employ suitable data collection and analysis strategies to identify successful programs and relevant programmatic approaches. The plan must be of sufficient detail and scientific rigor to serve as a justification for future DHHS evaluation funding. The plan must be prepared using a format provided by the project officers and based on requirements established at http://www3.od.nih.gov/ospde/funds_02.htm.
12. The final evaluation plan must be delivered in hard copy and electronically in Microsoft Word format to the project officers within two months of the date of the workshop.

Application of Findings: The findings from these studies may be incorporated into future policies in this area. The findings will affect not only the RCR requirement on T32 research training grants but will also affect the requirement that is currently embedded in all NIH fellowships and career development awards. In the future, the findings may shape the development of future ORI policy decisions.

G. EVALUATION FACTORS

1. **Personnel** - Reviewers will consider the experience of personnel in performing the tasks outlined in the Task Order Description. This discussion will evaluate documentation provided relating the knowledge and skills of the proposed personnel proposed to the various duties required in this project. The reviewers will especially consider any documentation and prior publications that demonstrate the experience of the evaluation expert to be designated as the moderator of the workshop and author of the comprehensive evaluation plan. **Weight – 35 points**
2. **Organizational Experience** – The organizational capabilities related to logistics support for workshops and the on-time development of written summaries of workshops will be considered by the reviewers. **Weight – 35 points**

3. **Management and Staffing** – The proposed staffing and management plans including the roles and responsibilities of all personnel assigned to the required tasks will be considered by the reviewers. **Weight - 15 points**
4. **Past Performance of the Organization and Personnel** – All documentation provided related to the past performance of the organization and the designated personnel on tasks relevant to this task will be considered by the reviewers. **Weight - 15 points**

The Government will award this task to the responsive Offeror whose proposal, in response to the RFTOP, will be most advantageous to the government. In weighting the factors which go into our final source selection, the overall technical evaluation including past performance will account for 80% and the evaluated cost will account for 20%.

